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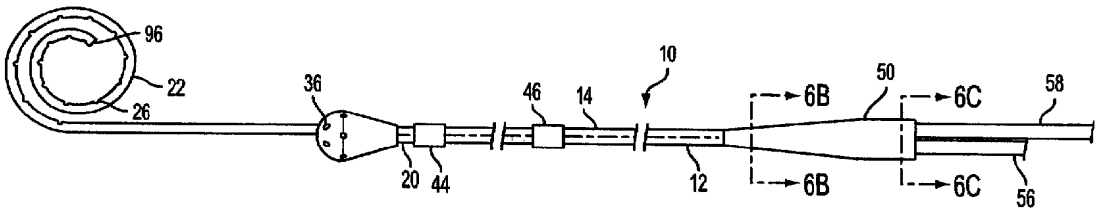

(57) Abstract: Continuous flow catheters, diffusers for catheters, catheters having a diffuser, and methods for continuous flow peritoneal dialysis are provided. The continuous flow catheter includes at least two lumens, of which one is short and the other is long. The long lumen is coiled and contains a plurality of openings. Another similar continuous flow catheter also includes a diffuser for the dispensing of fluid in a diffused manner. The catheters are used for peritoneal dialysis. The diffuser, for use with a catheter, has a plurality of openings for the dispensing of matter in a diffused manner. One method for continuous flow peritoneal dialysis includes creating an incision in the body of the user and separating the anatomical layers, making a circular suture in the peritoneal membrane, making an incision in the peritoneal membrane, inserting the catheter, and tightening the parietal peritoneum. Another method additionally includes anesthetizing the skin and peritoneal surface, making a lateral incision in the skin of the user, creating a skin tunnel, passing the catheter through the skin tunnel, connecting attachments to the catheter, and suturing the skin incision. The methods also include providing a catheter having a diffuser.

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Title

Catheter

Cross-Reference to Related Application

This application claims the benefit of U.S. Provisional Application Ser. No. 60/327,515, filed on Oct. 5, 2001, entitled "Continuous Flow Peritoneal Dialysis," of which Claudio Ronco and Angela Gloukhoff are the inventors.

Background of the Invention

Continuous flow peritoneal dialysis is a technique which utilizes a certain amount of fluid, generally dialysate, which is constantly present in the abdomen. Continuous flow peritoneal dialysis previously known in the art has utilized two single lumen peritoneal dialysis catheters or a modified large bore hemodialysis catheter. The inflow and uptake catheters enable the inflow and outflow to remain constant. However, high dialysate flow rates and re-circulation due to channeling or poor mixing inside the peritoneal cavity are problems associated with continuous flow peritoneal dialysis.

In the continuous flow peritoneal dialysis technique, the peritoneal dialysis solution is either utilized in a single pass or a re-circulation loop. Various re-circulation systems, such as sorbent cartridges or dialyzers, are known. A problem has been the quick drainage of fresh solution before coming into contact with the peritoneal exchange surface.

Regeneration systems include utilizing a batch of moderate volume prepared fluid and re-circulating the fluid until it saturates. Another method provides an initial fixed volume of commercial dialysis solution for priming, followed by continuous regeneration of the spent dialysate. Regeneration can be performed either by a hemodialysis filter or by absorption. Another method is preparation of solutions from water in concentrate with on-line ultra-filtration.

The proximal ends of the two lumens are attached to a dialysate regeneration means, which are well known in the art. Regenerated dialysate, or fresh dialysate, are introduced into the abdomen

through one of the catheters, which is connected to a means for providing regenerated or fresh dialysate, which is well known in the art.

For all of the aforementioned reasons, it is important to have a continuous flow peritoneal dialysis catheter and method which effectively allow the dialysate to mix into the peritoneum while reducing trauma to the peritoneal walls. In addition, it is important to have catheters, and diffusers for catheters, that gently dispense the matter flowing through the catheter.

Summary of the Invention

The present invention relates generally to continuous flow catheters with at least two lumens, one of which is a short lumen, and the other of which is a long lumen. In this invention, the long lumen, which is the uptake lumen, is coiled. It may have a plurality of openings, generally located on the inside of the coil, for the intake of matter flowing through the catheter.

The catheter also may include a diffuser, which is located over the distal end of the short lumen, for dispensing matter into the body of the user. The long lumen may extend beyond, and/or through, the diffuser.

The catheter may also include a hub at the proximal ends of the at least two lumens. The hub may be passable subcutaneously through the body of the user of the catheter, or the hub may be detachable.

The catheter of the current invention may be used for peritoneal dialysis.

In addition, the catheter may include at least one cuff located proximally to the peritoneal membrane for the adherence of subcutaneous tissue. The catheter may contain lumens which are "D" shaped.

The current invention also relates to diffusers for a catheter, as well as catheters having a diffuser. The diffuser has an interior portion and an exterior portion and at least one opening for the dispensing of matter into the body of the user. In addition, the diffuser may have a plurality of

openings through which the matter may be dispensed into the body of the user in a diffused manner. The plurality of openings may be located radially around the sides of the diffuser in a generally perpendicular manner to the longitudinal axis of the catheter. The shapes of the diffuser generally consist of cylindrical, teardrop, bell, round, oval, semi-round, semi-oval and a combination of shapes. The diffuser, and catheter having a diffuser, may be used on a catheter used for a continuous flow peritoneal dialysis.

The current invention also includes methods for a continuous flow peritoneal dialysis which include the steps of creating an incision in the body of the user and separating the anatomical layers, making a circular suture in the peritoneal membrane, making an incision in the peritoneal membrane, inserting the catheter, and tightening the parietal peritoneum. The method also may include anesthetizing the skin and peritoneal surface. In addition, the method may include making a lateral incision in the skin of the user, creating a skin tunnel, passing the catheter through the skin tunnel, connecting attachments to the catheter, and suturing the skin incision. The method may also include providing a catheter having a diffuser.

Brief Description of the Drawings

The accompanying drawings, which are incorporated in and form a part of the specification, illustrate the embodiments of the present invention, and together with the description, serve to explain the principles of the invention. In the drawings, the same reference numerals are employed for designating the same elements throughout the several figures.

FIG. 1A is a perspective view of a cylindrically shaped diffuser;

FIG. 1B is a side elevational view of a round and/or oval diffuser;

FIG. 1C-1 is a perspective view of a semi-oval shaped diffuser having a "D" shaped long lumen;

FIG. 1C-2 is a perspective view of a semi-round shaped diffuser having a round shaped long lumen;

FIG. 1D is a perspective view of a teardrop shaped diffuser;

FIG. 1E is a side elevational view of a bell shaped diffuser;

FIG. 2A is a top elevational view of a catheter with a diffuser and with no hub;

FIG. 2B is a top elevational view of a catheter with a diffuser and a hub;

FIG. 2C is a top elevational view of a catheter with a diffuser and a detachable hub;

FIG. 2D is a top elevational view of a catheter with a diffuser and with an optional hub of any kind;

FIG. 3 is a top elevational view of a catheter without a diffuser and with an optional hub of any kind;

FIG. 4 is a cross section of a diffuser;

FIG. 5A shows the catheter in utility;

FIG. 5B is a view of the diffuser in utility;

FIG. 5C is a view of a tunneled proximal end;

FIG. 5D is a view of a tunneled proximal end;

FIG. 6A is a cross section of a hub;

FIG. 6B is a cross section of the double "D" lumens in the hub;

FIG. 6C is a cross section of the extenders in the hub;

FIG. 7 is a flow chart of a method for continuous flow peritoneal dialysis;

FIG. 8A is a side view of the long lumen extended;

FIG. 8B is a cross section showing two double "D" shaped lumens; and

FIG. 8C is a cross section showing two round shaped lumens.

Detailed Description of the Invention

In describing embodiments of the invention illustrated in the drawings, specific terminology will be used for the sake of clarity. However, the invention is not intended to be limited to the specific terms so selected, and it is to be understood that each specific term includes all technical equivalents which operate in a similar manner to accomplish a similar purpose. The words "proximal," "distal," "short" and "long" are used herein for exemplary purposes, and are not to be taken as a limitation on the present invention. The words "proximal" and "distal" refer to directions away from and closer to, respectively, the insertion tips of the first and second lumens according to the present invention. The words "short" and "long" designate the length of lumens relative to one another.

Reference is now made to **FIGS. 2A, 2B, 2C, 2D**, and **3** which show the catheter **10, 10'** of the current invention. As seen in these figures, the catheter contains at least two lumens, a first lumen **12** and a second lumen **14**. The second lumen **14** is longer than the first lumen **12**. For explanatory purposes, the second lumen **14** also is referred to as a long lumen **14** and the first lumen **12** also is referred to as a short lumen **12**. Each lumen has a proximal end **16, 18** and a distal end region, **20, 22**. Each of the distal end regions, **20, 22** of each of the at least two lumens **12, 14** has at least one opening, **24, 26** for the passage of matter **42** into or out of the body of the user of the catheter **10, 10'**. Matter **42** passes through the longitudinal lumen channel **112** defined by the lumen wall **90**.

The catheter **10, 10'** of the present invention can be adapted for use in various applications in which bodily fluids, medicaments or other solutions are introduced into and removed from the body such as perfusion, infusion, plasmapheresis, hemodialysis, chemotherapy, and the like. The area to be catherized may be the peritoneum, and may be any suitable area within the body. Other areas in which the catheter **10, 10'** may be used include, for example, any abscess cavity, post-operative cavity, and other areas of the body including inter-abdominal, sub-diaphragmatic and sub-hepatic

areas. It should be understood by one of ordinary skill in the art from this disclosure that these areas are exemplary, and that the catheter **10, 10'** may be used to remove or introduce matter in various areas to be catherized. In addition, it will be understood by one skilled in the art based on this disclosure, that the catheter **10, 10'** can be configured and adapted by increasing or decreasing the catheter size and/or number of catheters and/or lumens such that the catheter **10, 10'** can be beneficially used for other medical applications in which matter is introduced into and/or removed from the body.

Matter **42** may pass into the body of the user of the catheter through the short lumen **12**, which also can be referred to as the delivery lumen. Matter may be removed from the body of the user of the catheter **10** through the long lumen **14**, which also can be referred to as the uptake or return lumen. However, it is to be understood that within the scope of the invention the long lumen **14** also may be a delivery lumen and the short lumen **12** may be an uptake lumen.

The long lumen **14** can be coiled and has at least one opening **26** for the passage of matter through the lumen. The at least one opening **26** can be at the distal end **96** of the lumen **14**. In addition, it is within the scope of this invention to place the at least one distal opening **26** along the side **98** of the distal end region **22** of the long lumen **14**.

The long lumen **14** may have a plurality of openings **26** along the side **98** of the distal end region **22** of the lumen.

The plurality of openings **26** also may be located along the side **98** of the distal end region **22** of the lumen in a manner whereby all of the plurality of openings **26** are located on the inside of the coiled distal end region **22** of the lumen. **FIG. 8A**, which extends the coil for exemplary purposes only, illustrates this embodiment. In addition, a distal opening **26,** optionally may be included at the end **96** of the distal end region **22** of the lumen **14**.

As seen in **FIG. 8B**, the lumens **12, 14** each may have a "D" shape. However, it is within the scope of the invention to have lumens **12, 14** that are round in shape, as seen in **FIG. 8C**. The lumen **12, 14** shapes as shown in **Figs. 8B** and **8C** are intended to be exemplary only of the variety of lumen shapes that can be used with the present invention. It will be understood, based on this disclosure, that the present invention is not limited to the configurations shown is **Figs. 8B** and **8C**. One skilled in the art will appreciate that all shapes of the lumens known in the art to be discovered are within scope of the invention. In addition, the lumens each may have shapes and sizes that vary from the other lumen or lumens.

Optionally, as known in the art, a radiopaque strip **94** may be included in the lumen wall **90** of either the short lumen **12** or the long lumen **14** to distinguish the lumens from one another, particularly at their proximal ends **16, 18**. Generally, the radiopaque strip **94** will be placed in the long lumen **14** as the longer length enables the user to more readily identify the radiopaque strip **94**.

Reference is know made to **FIGS. 1A** through **1E, 2A** through **2D, 4, 5A** and **5B**, which illustrate a diffuser **30.** It is to be noted that the embodiment of the catheter **10'** that is illustrated in **Fig. 3** does not contain a diffuser. The diffuser **30** may be added to the catheter **10** and located over the at least one distal opening **24** in the short lumen **12**. The long lumen **14** extends beyond the diffuser **30** more distally into the body of the user of the catheter. As seen most clearly in **FIGS. 1C-1, 1C-2,** and **4**, the long lumen **14** may extend through the diffuser **30**. In **FIG. 1C-1**, the long lumen **14** is "D" shaped. In **FIG. 1C-2**, the long lumen **14** has a round shape.

The diffuser **30** has an interior portion **32** and an exterior portion **34** and at least one opening **36** between the interior portion **32** and the exterior portion **34**. The matter **42** being dispensed in the body of the user flows through the short lumen **12** and into the diffuser **30** at the distal end opening **24** of the lumen **12**. Thereafter, the matter **42** flows through the at least one opening **36** of the diffuser and into the body of the user.

The diffuser **30** may have a plurality of openings **36** through which the matter **42** enters the body of the user in a diffused manner. In addition, the plurality of openings **36** may be located radially around the sides of the diffuser **30** in a generally perpendicular manner to the longitudinal axis of the catheter **10**.

The catheter **10** of the current invention may be used for continuous flow peritoneal dialysis. In peritoneal dialysis, the matter **42** flowing through the catheter may be dialysate. The diffuser **30** of the current invention enables a gentle interaction on the peritoneal structures from the effects of high dialysate flow rates, and enables the dialysate solution to readily mix into the peritoneal cavity **40**. When used for continuous flow peritoneal dialysis, the radially located openings **36** allow dialysate **42** to exit perpendicularly generally 360 degrees from the diffuser.

FIGS. 1A through **1E** illustrate various shapes in which a diffuser **30** may be formed. **FIG. 1A** illustrates a cylindrical shape, **FIG. 1B** illustrates an oval and/or round shape, **FIG. 1C-1** illustrates a semi-oval shape, **Fig. 1C-2** illustrates a semi-round shape, **FIG. 1D** illustrates a teardrop shape and **FIG. 1E** illustrates a bell shape. In addition, a diffuser **30** may be made of combinations of the shapes illustrated in **FIGS. 1A – 1E**. The diffuser **30** configurations as shown in **FIGS. 1A** through **1E** are intended to be exemplary only of the variety of configurations achievable with the present invention. It will be understood, based on this disclosure, that the present invention is not limited to the configurations shown in **FIGS. 1A** through **1E**.

When used for continuous flow peritoneal dialysis, the diffuser **30** provides even disbursement of the dialysate **42**. The plurality of openings **36** diffuse the delivery pressure of the dialysate **42**, which can provide a gentle interaction on the peritoneal membrane **38**.

It is to be understood that the dimensions of the invention may be varied for different size catheters, embodiments, and different characteristics unique to the user of the catheter. Examples of dimensions that may be used include the following: the proximal end of the diffuser **30** may be

located less than 1mm from the peritoneal membrane 38. Also, the distance between the distal end of the diffuser **30** and the beginning of the spiral at the distal end region **22** of the long lumen **14** may be approximately 15 cm in length. While the length of the spiral distal end region **22** of the long lumen **14** may vary, its length may be approximately 8.875 inches. Lumen resistance may yield in the range of 100 to 300 ml/min. When the diffuser **30** is cylindrical in shape, the width **28** of the cylinder **1AI** may be .5 cm long. While any number of openings **36** can be used, diffusers **30** may have openings in numbers ranging from six to twenty-four. It is to be understood that these dimensions are exemplary only, and are not to be taken as limitations on the invention.

As clearly illustrated in **FIG. 4**, the interior portion **32** of the diffuser **30** may have a proximal bonding region **82** and a distal bonding region **84**, which are regions onto which the lumen wall **90** of the long lumen **14** may be bonded to the diffuser **32**. The bonding may be accomplished by means of glue, adhesive, heat bonding, or other means currently known in the art or to be discovered.

Reference is now made to **FIG. 5A**, which shows the general location of the catheter **10** in the peritoneum **100**, when the catheter **10** is used for continuous flow peritoneal dialysis. The diffuser **30** is located just distally to the peritoneal membrane **38**. The coiled distal end region **22** of the long lumen **14** is located in the lower Douglas cavity **92** of the peritoneum **100**. In use, the catheter **10** separates the delivery and return of the dialysate **42**. As a result, there is minimal recirculation of the spent dialysate **42**. In use, the fresh dialysate **42** enters the peritoneum **100** through the diffuser **30**. The dialysate **42** passes through the peritoneum **100** where the necessary physiological and chemical processes occur, and which turn the fresh dialysate into spent dialysate. Constant intra-peritoneal volume can be maintained with high dialysate flow rates to maintain a high solute concentration gradient between plasma and continuously renewed dialysate solution **42**. The

spent dialysate **42** is aspirated back out of the peritoneum **100** through the at least one opening **26** of the long lumen **14**.

The coiled design of the distal end region **22** of the long lumen **14** increases the bulk tubing which separates the parietal and visceral layers of the peritoneum **100** from obstructing the at least one distal opening **26** for outflow of the spent dialysate **42**. The use of a plurality of openings **26** can increase the outflow rate. The use of a coiled long lumen **14** distal end region **22** is preferred for peritoneal dialysis because it is more gentle to the viscera than the tip of a straight lumen.

Preferably, the catheter **10, 10'** is made of a low durometer silicone. However polyurethane or other biocompatible materials known in the art or to be developed may also be used. Low durometer silicone is preferable because of its biocompatibility and softness, which is beneficial for use in the peritoneum **100**, which is a relatively soft body structure. In addition, low durometer silicone is flexible in a large range of temperatures and has no clinically harmful leachable plasticizers.

The first lumen **12**, the second lumen **14**, and additional lumens in catheters having more than two lumens, and diffuser **30** may be made of a biocompatible plastic or elastomer, more preferably from a biocompatible elastomer. Suitable biocompatible plastics include materials such as, for example, polyethylene, homopolymers and copolymers of vinyl acetate such as ethylene vinyl acetate copolymer, polyvinylchlorides, homopolymers and copolymers of acrylates such as polymethylmethacrylate, polyethylmethacrylate, polymethacrylate, ethylene glycol dimethacrylate, ethylene dimethacrylate and hydroxymethyl methacrylate, polyurethanes, ployvinylpyrrolidone, 2-pyrrolidone, polyacrylonitrile butadiene, polycarbonates, polyamides, fluoropolymers such as homopolymers and copolymers of polytetrafluoroethylene and polyvinyl fluoride, polystyrenes, homopolymers and copolymers of styrene acrylonitrile, cellulose acetate, homopolymers and copolymers of acrylonitrile butadiene styrene, polymethylpentene, polysulfones, polyesters,

polyimides, polyisobutylene, polymethylstyrene and other similar compounds known to those skilled in the art. It should be understood that these possible biocompatible polymers are included above for exemplary purposes and should not be construed as limiting. If a biocompatible polymeric material is used to form the catheter **10, 10'** it is most preferred that the polymeric material includes a polyurethane or a polyolefin polymeric material having a preferably soft durometer, as specified below.

Suitable, preferred, biocompatible elastomers for use in forming the catheters **10, 10'** include biocompatible elastomers such as medical grade silicone rubbers, polyvinyl chloride elastomers, polyolefin homopolymeric and copolymeric elastomers, urethane-based elastomers, and natural rubber or other synthetic rubbers. The catheter **10, 10'** may be made of the elastomeric material such that they are flexible, durable, soft, and easily conformable to the shape of the area to be catheterized and/or the subcutaneous area and minimize risk of harm to vessel walls. If the catheter **10, 10'** is used for hemodialysis applications, they may be formed of a soft silicone elastomer which has a hardness of at least about 80-A on a Shore durometer scale. Such an elastomer is available from Dow Corning, and can include 20% barium sulfate in the elastomer to provide radiopacity. While it is preferred to have a higher Shore durometer hardness if a biocompatible elastomer is used, particularly for hemodialysis, it is also possible to make a device from an elastomer having a lower Shore durometer hardness without departing from the spirit of the invention. It will be understood, based on this disclosure, that the catheter **10, 10'** may also be radiopaque depending on its intended use.

Reference is now made to **FIGS. 2B, 2C, 2D, 3, 5C, 5D** and **6A** through **6C**, which show the invention with a hub **50**, which is optional. When a hub **50** is provided, the proximal ends **16, 18** of the at least two lumens **12, 14** are located in the hub **50**. The lumens **12, 14** may be attached to the hub **50** in a nonremovable manner, as seen in **FIG. 2B**. Alternatively, the lumens **12, 14** may be

attached to a detachable hub **50'**, as seen in **FIG. 2C**. Detachable hubs are disclosed in a pending application, U.S. Provisional Application Serial No. 60/329,593, entitled "Detachable Hub," which is incorporated herein by reference. In addition, as illustrated in **FIGS. 2D** and **3**, the use of all hubs **110** currently known in the art or to be discovered are within the scope of the invention. However, as illustrated in **FIG. 2A**, the hub is optional, and the hubs included for exemplary purposes should not be construed as limiting. One skilled in the art will appreciate that the catheter **10, 10'** of the current invention may be used with a hub **50**, a detachable hub **50'**, with no hub, or with hubs **110,** or other attachments **110**, currently known in the art or to be discovered.

In an embodiment of the invention, as seen in **FIG. 2B, 5C, 5D** and **6A – 6C**, a non-removable hub **50** may be utilized. As seen in these figures, the proximal ends **16, 18** of the at least two lumens **12, 14** end in the hub **50**. In addition, the distal ends of extenders **56, 58** also end in the hub **50**. In this embodiment, when the lumens **12, 14** are "D" shaped, the proximal end openings **102, 104** of the lumens **12, 14** each are "D" shaped. Further, as seen in the embodiment illustrated in **FIGS. 6A** through **6C**, the distal openings **106, 108** of the extenders **56, 58** each may have a round shape. The extension distal end openings **106, 108** and the proximal end openings, **102, 104** of the at least two lumens **12, 14** are brought into fluid communication with each other via hub channels **52, 54** molded in the hub **50**. The hub **50** is molded around a removable interior pin (not shown) that is round at one end and "D" shaped at the other end. The shapes, sizes, and number of the lumens and extenders utilized with the hub **50** are exemplary, and not intended to be limiting. The extension proximal ends (not shown) are preferably connected to respective female luer locks (not shown) in a conventional manner. If decided, the female luer locks may be substituted with any suitable type of quick connect fittings, ferrule connectors, threadable connectors, or any connection means known in the art or to be discovered to achieve the flow of matter through the catheter **10, 10'.** The extenders, as known in the art, may be connected in fluid communication to respective

fluid inlets and outlets of the dialysis unit, other fluid transfer equipment, or other apparatus needed to carry out the purpose for the catheter **10, 10'**.

As previously mentioned, the hub **50, 50'** and extenders **56, 58** of the catheter **10, 10'** are optional. The catheter **10, 10'** of the present invention can be formed simply as at least two lumens **12, 14**. The proximal ends **16, 18** of the lumens could be made connectable to dialysis equipment or other apparatus by providing luers or other connectors to the proximal ends **16, 18** of the lumens without a hub or additional extenders.

When the catheter **10, 10'** has a hub **50** that is not detachable, generally, the hub **50** will be passable through the subcutaneous layer **48** of body of the user of the catheter. As seen in **FIGS. 5C** and **5D**, the proximal ends **16, 18**, hub **50** and extenders **56, 58**, may be passed through a subcutaneous tunnel in the subcutaneous layer **48** of the body using various tunneling techniques. The proximal ends **16, 18**, hub **50** and extenders **56, 58** may be inserted in a tunnel entrance incision **86** and tunneled through the subcutaneous layer **48** to the tunnel exit incision **86**. Alternatively, the lumen proximal ends **16, 18**, the hub **50** and the extenders **56, 58** may be inserted in the catheter entrance incision **110** and tunneled through the subcutaneous layer **48** to a tunnel exit incision **86**. In like manners, the catheters **10, 10'** that do not have hubs or that have detachable hubs **50'**, the lumen proximal ends **16, 18** may be subcutaneously tunneled.

Reference is now made to **FIGS. 2A** through **2D, 3, 4**, and **5A – 5D**, which illustrate the inclusion of at least one cuff **44**, which is optional. In addition, a second cuff **46** may also be included, which is optional. The at least one cuff **44**, as known in the art, is made of a material, generally polyester, onto which the tissue of the user of the catheter may grow in order to secure the catheter **10, 10'** to the body of the user. A cuff **44** is located just proximally to the peritoneal membrane **38**, when the catheter **10, 10'** is used for continuous flow peritoneal dialysis. The cuff **44** may be located between 0 and 5 mm proximally from the peritoneal membrane **38**. If the peritoneal

membrane **38** is sutured at the incision site of the catheter **10, 10',** added space may be needed because the suture, when pulled, may create folds in the membrane **38**. Preferably, the space between the diffuser **30** and the cuff **44** will be in the range of between .5 and 10 mm. The range of distance between the first cuff **44** and the second cuff **46**, preferably will be 10 cm. It is to be understood that the dimensions of the cuffs **44, 46** may be varied for different size catheters, embodiments, and different characteristics unique to the user of the catheter. The dimensions listed are not intended to be limiting, rather they are included for exemplary purposes.

As seen in **FIG. 5C**, a second cuff **46** may located under the skin distally to the exit hole **86** for the catheter **10, 10'**.

Reference is now made to **FIG. 7**, which is a flowchart for the method for continuous flow peritoneal dialysis of the current invention. The method includes creating an incision in the body of the user and separating anatomical layers until the peritoneum is found **62;** making a circular suture in the peritoneal membrane **64;** inserting the distal end of the catheter into the Douglas cavity of the peritoneum, guided by a semi-rigid wire inside the outflow lumen, and tightening the parietal peritoneum between the diffuser and cuff by tightening the circular suture in the peritoneal membrane **68**. In addition, the method may include, anesthetizing under the skin down to the peritoneal surface with a syringe **60.** Also, the method may include making a lateral incision in the skin of the user **70**; creating a subcutaneous tunnel, also known as a skin tunnel **72;** passing the proximal end of the catheter subcutaneously through the skin tunnel **74,** which may be accomplished by means of a tunneler; attaching connecting attachments to the lumens **76**; and suturing the incision in the skin **78**.

The method may also include providing a catheter **10** that has a diffuser **30**.

The incision of step **62** may be about 3 cm long, and the incision of step **70** may be about 10 cm long. It is to be understood that the dimensions of the incisions may be varied for different size

catheters, embodiments, and different characteristics unique to the user of the catheter. The dimensions listed are not intended to be limiting, rather they are included for exemplary purposes.

A sheath (not shown), as commonly known in the art, may be inserted over the diffuser before insertion of the catheter **10** into the body. Because the diffuser **30** preferably is made of a low durometer silicone, it may be easily compressed into the optional sheath. The sheath diminishes the volume of the diffuser **30**, which may enable the insertion of the catheter **10,** including the diffuser **30**, utilizing a smaller incision than would be possible without use of a sheath. A Quill sheath is commonly known in the art, and may be used for a catheter **10** that does not have a hub. If the catheter **10** has a hub **50,** which is not removable, a tear-away sheath, which is commonly known in the art, may be used.

When a catheter **10, 10'** having a hub **50** which is not detachable is passed through the skin tunnel subcutaneously **76**, the subcutaneous layer **48** will have to stretch to enable the hub **50** to pass. Normally, the elasticity of the subcutaneous layer **48** will enable the subcutaneous tissue to encapsulate the lumens **12**, **14** after passage of the hub **50**. When a detachable hub **50^1** is utilized on the catheter **10, 10'**, the hub **50^1** is among the attachments connected to the catheter during the step **76** of connecting attachments to the catheter.

As known in the art, the open ends of the luer locks may be connected in fluid communication to respective fluid inlets and outlets of the dialysis unit, or other fluid transfer equipment in order to begin dialysis.

Although the invention has been described and illustrated by various embodiments, it will be apparent to those of ordinary skill in the art that changes and modifications could be made which clearly fall within the scope of the invention. It is understood, therefore, the invention is intended to be protected broadly within the spirit and scope as defined by the appended claims.

What is claimed is:

1. A continuous flow catheter, said catheter comprising at least two lumens, each of said at least two lumens having a proximal end and a distal end region, each of the distal end regions of each of said at least two lumens comprising at least one opening for the passage matter into or out of the body of the user of the catheter, at least one of said at least two lumens being a first lumen and at least one of said at least two lumens being a second lumen, said second lumen being longer than said first lumen, wherein said distal end region of said second lumen is coiled.

2. The continuous flow catheter of claim 1, wherein matter passes into the body of the user of the catheter through said first lumen, and matter is removed from the body of the user of the catheter through said second lumen.

3. The continuous flow catheter of claim 2, said catheter further comprising a diffuser, said diffuser located over the at least one opening in said first lumen.

4. The continuous flow catheter of claim 3, said second lumen extending beyond said diffuser more distally into the body of the user of the catheter.

5. The continuous flow catheter of claim 4, said second lumen extending through said diffuser.

6. The continuous flow catheter of claim 1, wherein said catheter is used for peritoneal dialysis.

7. The continuous flow catheter of claim 6, said catheter further comprising at least one cuff.

8. The continuous flow catheter of claim 7, wherein one of said at least one cuffs is located proximally to the peritoneal membrane.

9. The continuous flow catheter of claim 1, said catheter further comprising a hub, said proximal ends of said at least two lumens located in said hub.

10. The continuous flow catheter of claim 9, wherein said hub is passable subcutaneously through the body of the user of the catheter.

11. The continuous flow catheter of claim 9, wherein said hub is detachable.

12. The continuous flow catheter of claim 1, wherein each said lumens is "D" shaped.

13. The continuous flow catheter of claim 1, wherein at least one of said at least two lumens contains a radiopaque strip.

14. The continuous flow catheter of claim 1, wherein said distal end region of said second lumen has at least one opening in the side of the lumen for the passage of matter.

15. The continuous flow catheter of claim 14, wherein said distal end region of said second lumen has a plurality of openings on the side of the lumen for the passage of matter.

16. The continuous flow catheter of claim 15, wherein said plurality of openings are located on the inside of said coil.

17. In a catheter for the passage of matter to the body of the user of the catheter, a diffuser through which matter is dispensed into the body.

18. The diffuser of claim 17, wherein said diffuser has an interior portion and an exterior portion and at least one opening between said interior portion and said exterior portion, the matter to be dispensed by said catheter entering said diffuser and being dispensed in the body through said at least one opening.

19. The diffuser of claim 18, wherein said diffuser has a plurality of openings and the matter being dispensed in a diffused manner.

20. The diffuser of claim 19, wherein said plurality of opening are located radially around the sides of said diffuser.

21. The diffuser of claim 17, wherein said diffuser has a shape selected from the group consisting of cylindrical, teardrop, bell, round, oval, semi-round, semi-oval and a combination of shapes.

22. The diffuser of claim 17, wherein said diffuser is on a catheter used for peritoneal dialysis.

23. The diffuser of claim 22, wherein said dialysis is continuous flow peritoneal dialysis.

24. A catheter comprising at least two lumens, each of said at least two lumens having a proximal end and a distal end region, each of the distal end regions of each of said at least two

lumens comprising at least one opening for the passage matter into or out of the body of the user of the catheter, one of said at least two lumens being a first lumen and one of said at least two lumens being a second lumen, said second lumen being longer than said first lumen; said matter passing into the body of the user of the catheter through said first lumen, and said matter being removed from the body of the user of the catheter through said second lumen; said catheter further comprising a diffuser, said diffuser located over the at least one opening in said first lumen and said second lumen extending more distally in the body of the user through said diffuser; said diffuser having an interior portion and an exterior portion and more than one opening between said interior portion and said exterior portion; the matter to be dispensed by said catheter entering said diffuser and being dispensed in the body through said more than one opening in a diffused manner.

25. The catheter of claim 24, wherein said catheter is used for continuous flow peritoneal dialysis.

26. The catheter of claim 25, wherein said distal end region of said second lumen is coiled, said distal end region of said second lumen having a plurality of openings for the passage of matter.

27. The catheter of claim 26, wherein said openings are located on the inside of said coil.

28. The catheter of claim 25, said catheter further comprising at least one cuff.

29. The catheter of claim 28, wherein one of said at least one cuffs is located proximally to the peritoneal membrane.

30. The catheter of claim 24, said catheter further comprising a hub, said proximal ends of said at least two lumens located in said hub.

31. The catheter of claim 30, wherein said hub is passable subcutaneously through the body of the user of the catheter.

32. The catheter of claim 30, wherein said hub is detachable.

33. The catheter of claim 24, wherein each said lumens is "D" shaped.

34. The catheter of claim 24, wherein at least one of said at least two lumens contains a radiopaque strip.

35. A continuous flow peritoneal dialysis catheter comprising at least two lumens, each of said at least two lumens having a proximal end and a distal end region, each of the distal end regions of each of said at least two lumens comprising at least one opening for the passage matter into or out of the body of the user of the catheter, one of said at least two lumens being a first lumen and one of said at least two lumens being a second lumen, said second lumen being longer than said first lumen; said matter passing into the body of the user of the catheter through said first lumen, and said matter being removed from the body of the user of the catheter through said second lumen; said catheter further comprising a diffuser, said diffuser located over the at least one opening in said first lumen and said second lumen extending more distally in the body of the user through said diffuser; said diffuser having an interior portion and an exterior portion and more than one opening between said interior portion and said exterior portion; the matter to be dispensed by said catheter entering said

diffuser and being dispensed in the body through said more than one opening in a diffused manner; said distal end region of said second lumen being coiled and having a plurality of openings located on the inside of said coil for the passage of matter; said catheter further comprising at least one cuff, said at least one cuffs being located proximally to the peritoneal membrane.

36. The continuous flow peritoneal dialysis catheter of claim 35, said catheter further comprising a hub, said proximal ends of said at least two lumens located in said hub.

37. The continuous flow peritoneal dialysis catheter of claim 36, wherein said hub is passable subcutaneously through the body of the user of the catheter.

38. The continuous flow peritoneal dialysis catheter of claim 36, wherein said hub is detachable.

39. The continuous flow peritoneal dialysis catheter of claim 35, wherein each said lumens is "D" shaped.

40. The continuous flow peritoneal dialysis catheter of claim 35, wherein at least one of said at least two lumens contains a radiopaque strip.

41. A method for continuous flow peritoneal dialysis, said method comprising:
creating an incision in the body of the user and separating the anatomical layers;
making a circular suture in the peritoneal membrane;
making an incision in the peritoneal membrane;
inserting the catheter;

tightening the parietal peritoneum;

42. The method for continuous flow peritoneal dialysis of claim 41, further comprising anesthetizing the skin and peritoneal surface.

43. The method for continuous flow peritoneal dialysis of claim 42, further comprising

making a lateral incision in the skin of the user;

creating a skin tunnel;

passing the catheter through the skin tunnel;

connecting attachments to the catheter; and

suturing the skin incision.

44. The method for continuous flow peritoneal dialysis of claim 41, wherein said method further comprises providing a catheter having a diffuser.

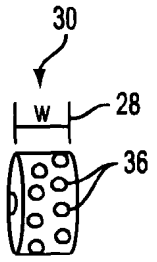


FIG. 1A

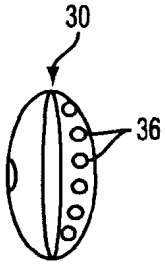


FIG. 1B

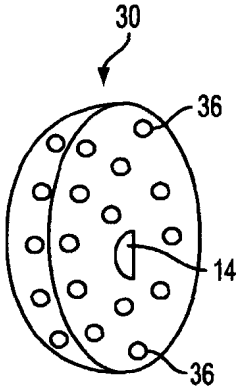


FIG. 1C-1

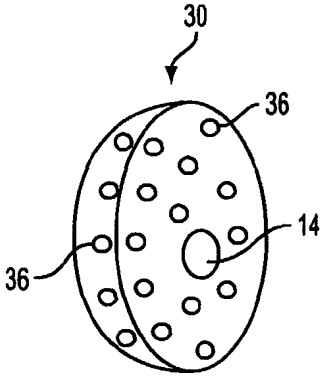


FIG. 1C-2

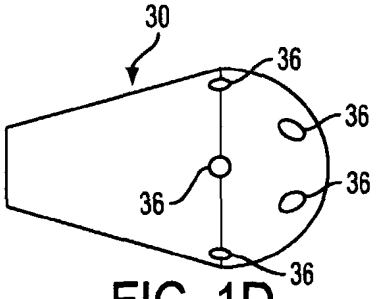


FIG. 1D

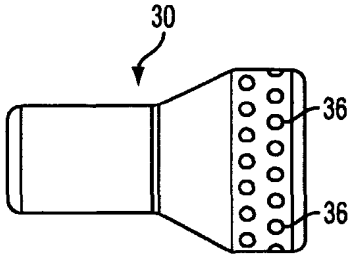
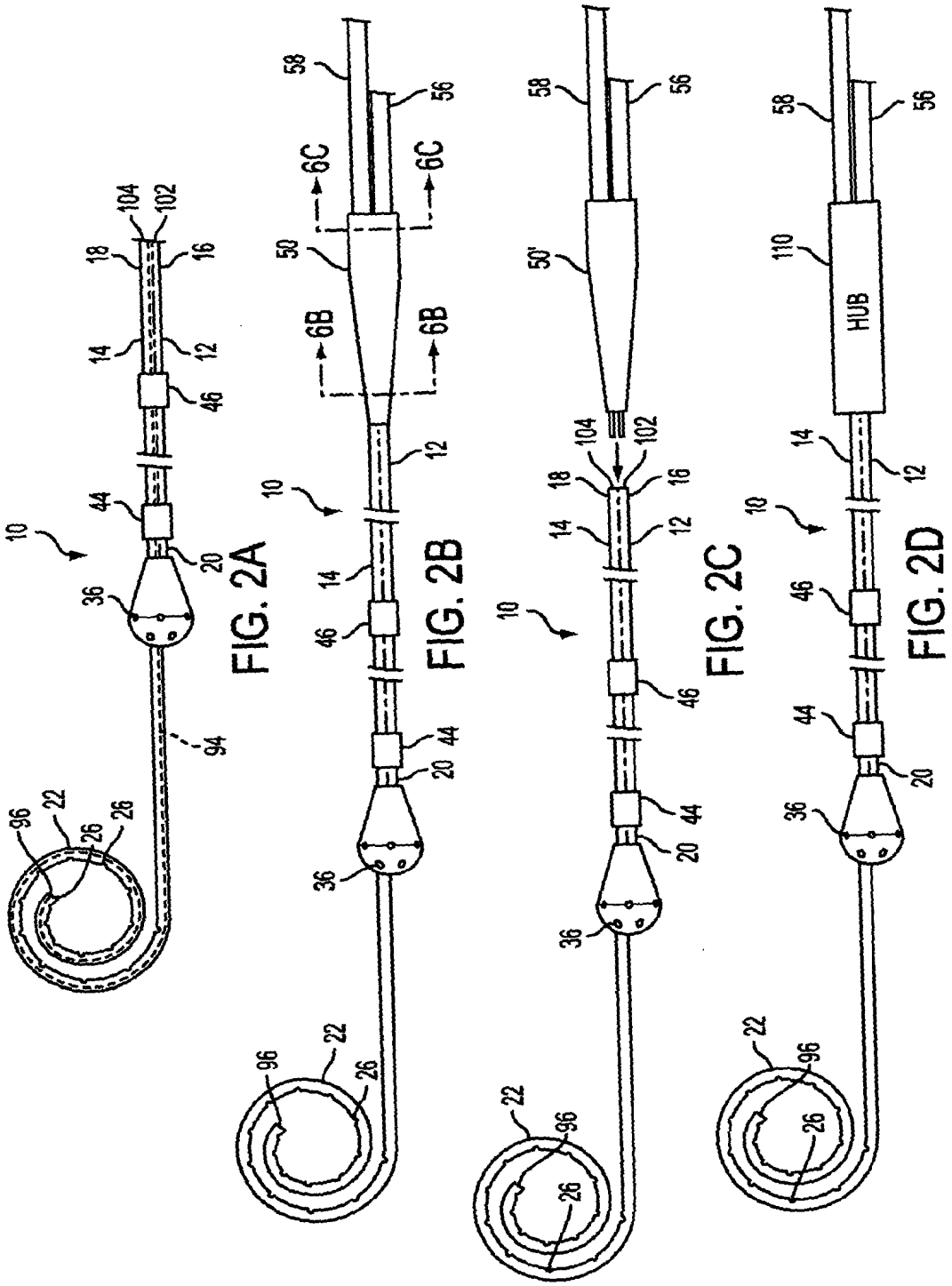


FIG. 1E


10
18
104
102
16
14
12
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44
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36
94
96
22
26
FIG. 2A
58
56
6C
6C
50
6B
6B
12
10
14
46
44
20
36
96
22
26
FIG. 2B
58
56
50'
104
102
18
16
14
12
10
46
44
20
36
22
96
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FIG. 2C
58
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HUB
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96
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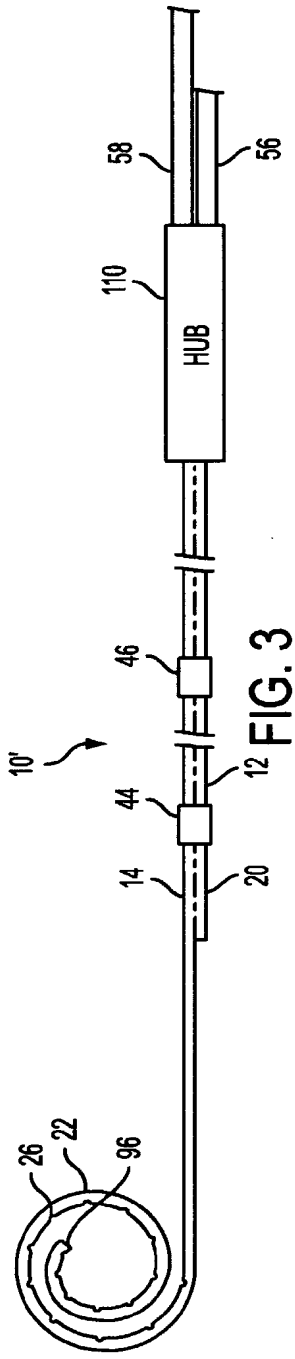
FIG. 2D


58
56
110
HUB
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10'
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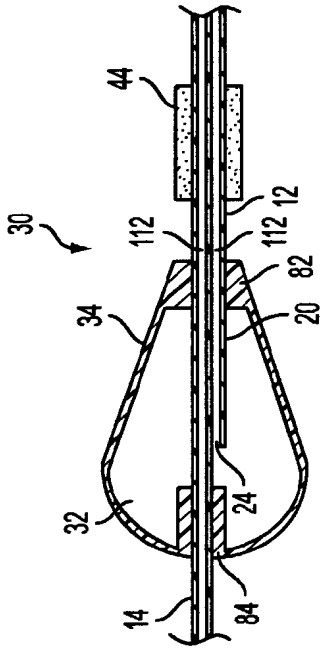
96

FIG. 3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14
84

FIG. 4

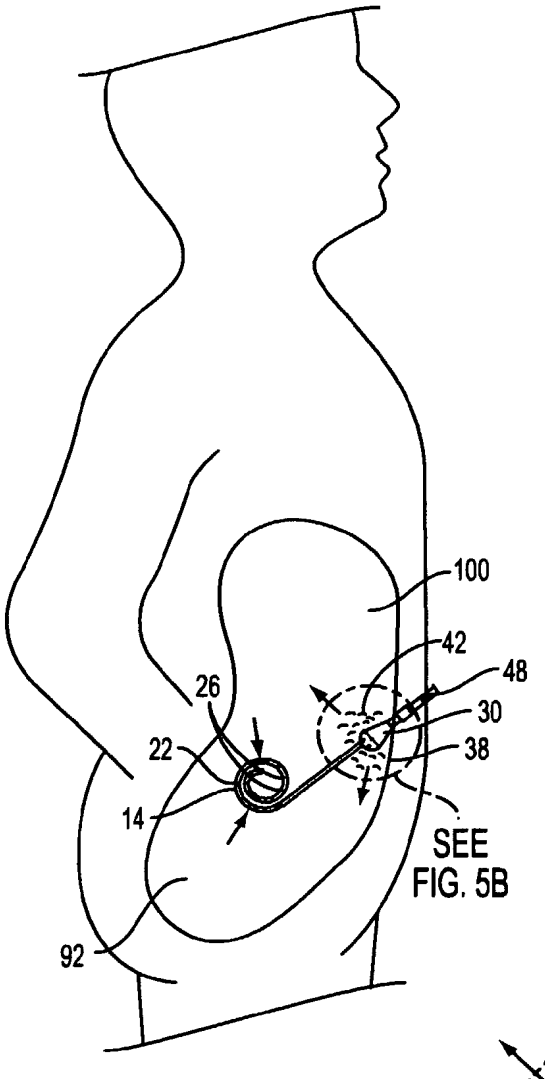

FIG. 5A

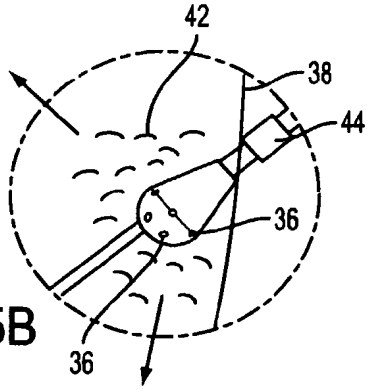

FIG. 5B

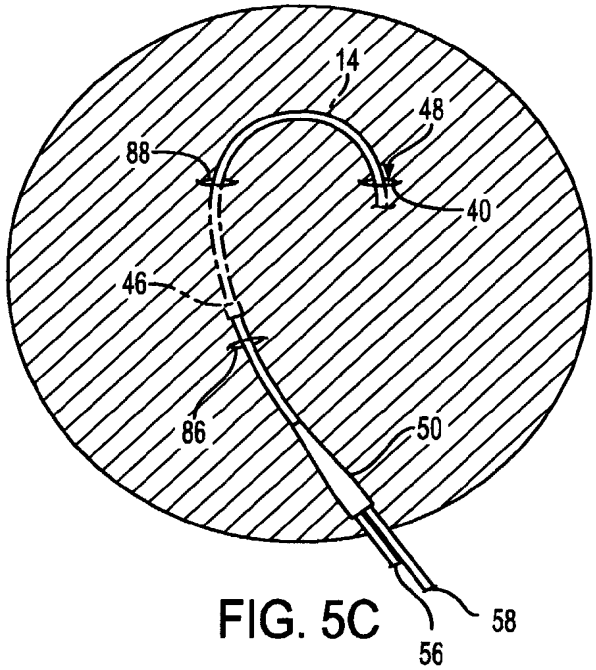

FIG. 5C

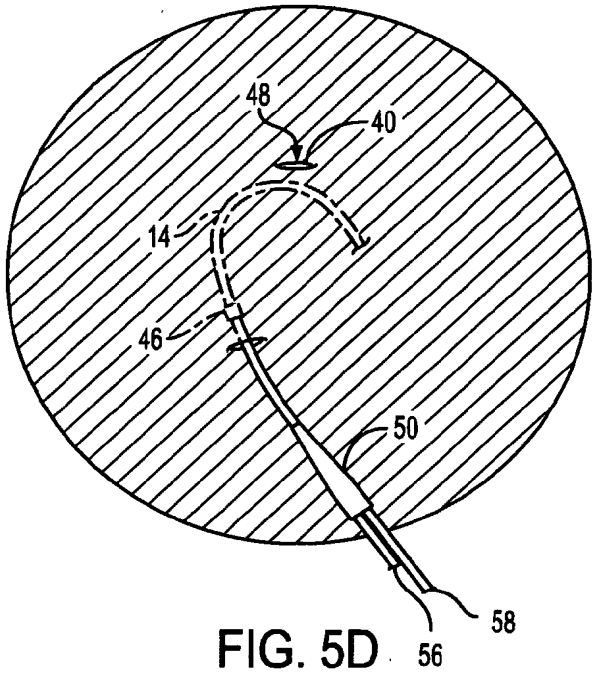

FIG. 5D

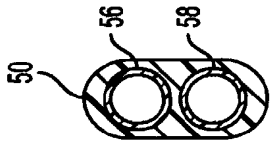

FIG. 6C

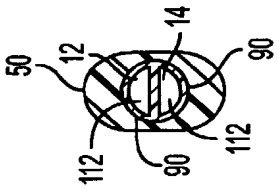

FIG. 6B

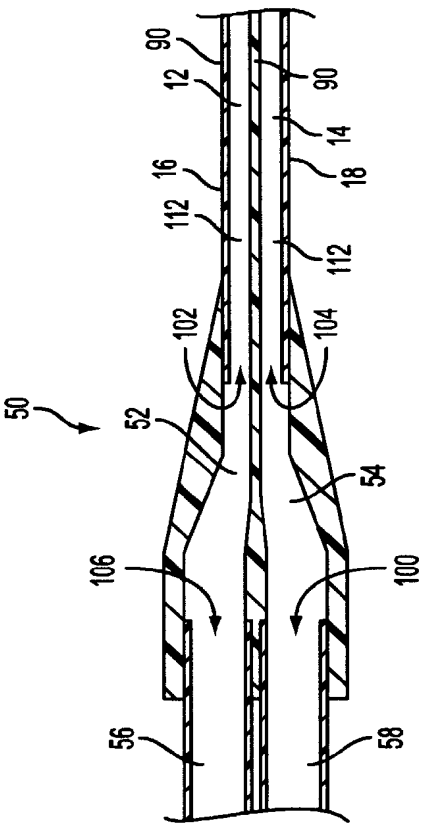

FIG. 6A

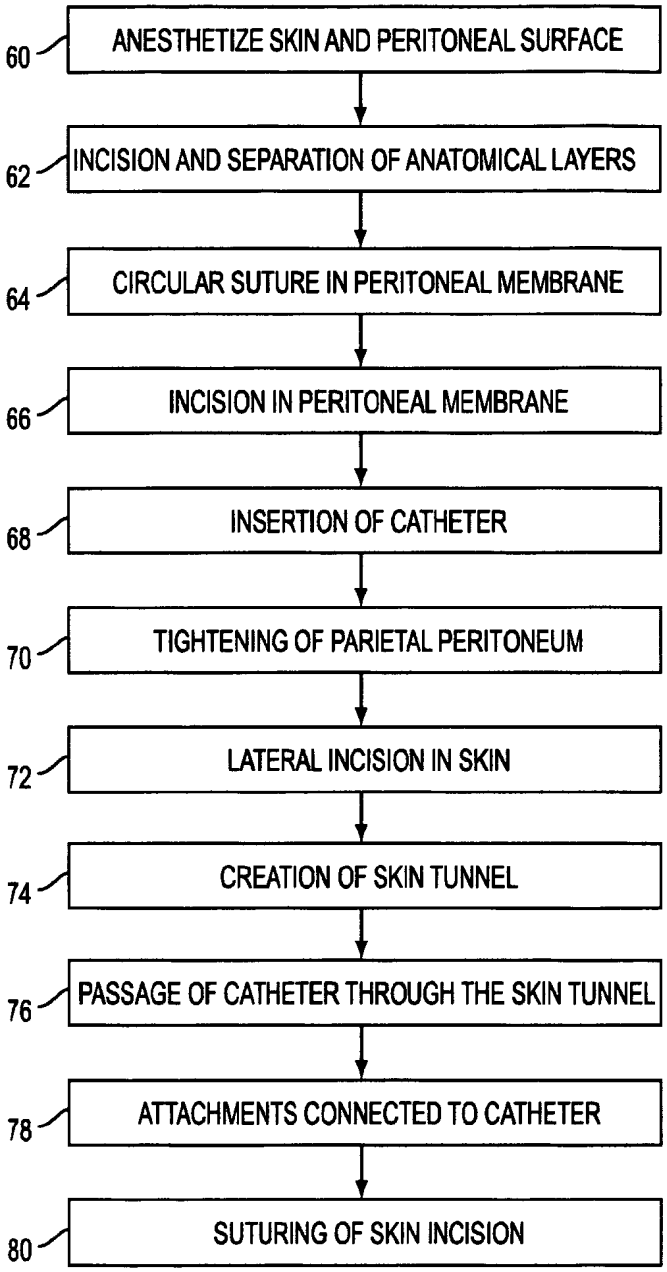
60
ANESTHETIZE SKIN AND PERITONEAL SURFACE
62
INCISION AND SEPARATION OF ANATOMICAL LAYERS
64
CIRCULAR SUTURE IN PERITONEAL MEMBRANE
66
INCISION IN PERITONEAL MEMBRANE
68
INSERTION OF CATHETER
70
TIGHTENING OF PARIETAL PERITONEUM
72
LATERAL INCISION IN SKIN
74
CREATION OF SKIN TUNNEL
76
PASSAGE OF CATHETER THROUGH THE SKIN TUNNEL
78
ATTACHMENTS CONNECTED TO CATHETER
80
SUTURING OF SKIN INCISION

FIG. 7

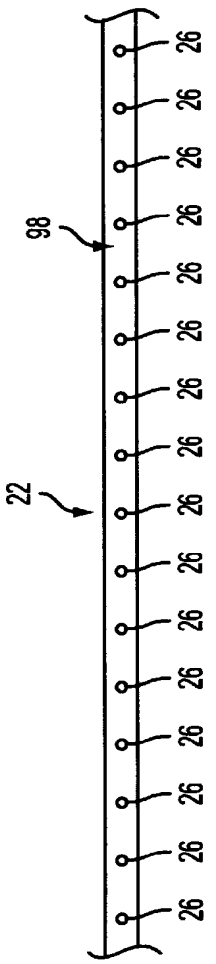

FIG. 8A

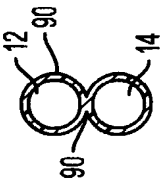

FIG. 8C

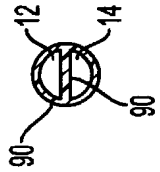

FIG. 8B